

LUPEROX® TBH70X

1. PRODUCT AND COMPANY IDENTIFICATION

Company

Arkema Inc.
900 First Avenue
King of Prussia, Pennsylvania 19406

Functional Additives

Customer Service Telephone Number: (800) 331-7654
(Monday through Friday, 8:00 AM to 5:00 PM EST)

Emergency Information

Transportation: CHEMTREC: (800) 424-9300
(24 hrs., 7 days a week)
Medical: Rocky Mountain Poison Center: (866) 767-5089
(24 hrs., 7 days a week)

Product Information

Product name: LUPEROX® TBH70X
Synonyms: TBHP
Molecular formula: C4 H10 O2
Chemical family: Organic peroxide - hydroperoxides
Product use: Polymerization inhibitor

2. HAZARDS IDENTIFICATION

Emergency Overview

Color: colourless to slightly yellow
Physical state: liquid
Odor: Bleach-like

***Classification of the substance or mixture:**

Flammable liquid., Category 3, H226
Organic peroxides, Type F, H242
Oral: Acute toxicity, Category 4, H302
Inhalation: Acute toxicity, Category 3, H331
Dermal: Acute toxicity, Category 3, H311
Skin corrosion, Category 1C, H314
Serious eye damage, Category 1, H318
Skin sensitisation, Category 1, H317
Germ cell mutagenicity, Category 2, H341
Chronic aquatic toxicity, Category 2, H411

*For the full text of the H-Statements mentioned in this Section, see Section 16.

GHS-Labeling

Hazard pictograms:



Signal word:

Danger**Hazard statements:**

H226 : Flammable liquid and vapour.
H242 : Heating may cause a fire.
H302 : Harmful if swallowed.
H311 + H331 : Toxic in contact with skin or if inhaled.
H314 : Causes severe skin burns and eye damage.
H317 : May cause an allergic skin reaction.
H341 : Suspected of causing genetic defects.
H411 : Toxic to aquatic life with long lasting effects.

Supplemental Hazard Statements:

Organic peroxide. Hazardous decomposition may occur.

LUPEROX® TBH70X**Precautionary statements:****Prevention:**

P201 : Obtain special instructions before use.
P202 : Do not handle until all safety precautions have been read and understood.
P210 : Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P220 : Keep/Store away from clothing/ combustible materials.
P233 : Keep container tightly closed.
P234 : Keep only in original container.
P240 : Ground/bond container and receiving equipment.
P241 : Use explosion-proof electrical/ ventilating/ lighting/ equipment.
P242 : Use only non-sparking tools.
P243 : Take precautionary measures against static discharge.
P261 : Avoid breathing gas/mist/vapours/spray.
P264 : Wash skin thoroughly after handling.
P270 : Do not eat, drink or smoke when using this product.
P271 : Use only outdoors or in a well-ventilated area.
P272 : Contaminated work clothing should not be allowed out of the workplace.
P273 : Avoid release to the environment.
P280 : Wear protective gloves/ protective clothing/ eye protection/ face protection.
P281 : Use personal protective equipment as required.

Response:

P301 + P312 : IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.
P301 + P330 + P331 : IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 : IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P304 + P340 : IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338 : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 : IF exposed or concerned: Get medical advice/ attention.
P310 : Immediately call a POISON CENTER or doctor/ physician.
P333 + P313 : If skin irritation or rash occurs: Get medical advice/ attention.
P363 : Wash contaminated clothing before reuse.
P370 + P378 : In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.
P391 : Collect spillage.

Storage:

P403 + P233 : Store in a well-ventilated place. Keep container tightly closed.
P405 : Store locked up.
P410 : Protect from sunlight.
P411 + P235 : Maximum storage temperature is specified on label and in section 7 of SDS. Keep cool.
P420 : Store away from other materials.

Disposal:

P501 : Dispose of contents/ container to an approved waste disposal plant.

Supplemental information:**Potential Health Effects:**

If swallowed, may cause severe irritation and injury to the mouth, throat and digestive tract.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Hydroperoxide, 1,1-dimethylethyl	75-91-2	70 %	H242, H226, H302, H311, H330, H314, H318, H317, H341, H411
Water	7732-18-5	30 %	Not classified

**For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

Inhalation:

If inhaled, remove to fresh air and keep at rest in a position comfortable for breathing. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately. Call a Poison Control Center.

Skin:

In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately. Call a Poison Control Center. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eyes:

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention immediately.

Ingestion:

If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel. Get medical attention immediately. If victim is fully conscious, give a cupful of water. Never give anything by mouth to an unconscious person. Rinse mouth.

5. FIREFIGHTING MEASURES

Extinguishing media (suitable):

Water spray, Foam, Dry chemical

Extinguishing media (unsuitable):

Water may be ineffective., Do not use a solid water stream as it may scatter and spread fire.

Protective equipment:

Fire fighters and others who may be exposed to products of combustion should wear full fire fighting turn out gear (full Bunker Gear) and self-contained breathing apparatus (pressure demand / NIOSH approved or equivalent).

Further firefighting advice:

Fight fire with large amounts of water from a safe distance.
Cool closed containers exposed to fire with water spray.
Closed containers of this material may explode when subjected to heat from surrounding fire.
After a fire, wait until the material has cooled to room temperature before initiating clean-up activities.
Do not allow run-off from fire fighting to enter drains or water courses.
Fire fighting equipment should be thoroughly decontaminated after use.

Fire and explosion hazards:

Contact with materials to avoid or exposure to temperatures exceeding the SADT may result in a self-accelerating decomposition reaction with release of flammable vapors which may autoignite.
When burned, the following hazardous products of combustion can occur:
Carbon oxides
Hazardous organic compounds

6. ACCIDENTAL RELEASE MEASURES**Personal precautions, Emergency procedures, Methods and materials for containment/clean-up:**

Prevent further leakage or spillage if you can do so without risk. Evacuate area of all unnecessary personnel. Ventilate the area. Eliminate all ignition sources. Avoid generation of vapors. Contain and collect spillage with non-combustible absorbent material such as sodium bicarbonate, sodium carbonate, calcium carbonate, clean sand or non-acidic clay and then wet down (dampen) the mixture with water. DO NOT USE peat moss. Sweep or scoop up using non-sparking tools and place into suitable properly labeled containers for prompt disposal. The sweepings should be wetted down further with water. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits.

Protective equipment:

Appropriate personal protective equipment is set forth in Section 8.

7. HANDLING AND STORAGE

Handling**General information on handling:**

Contact with materials to avoid or exposure to temperatures exceeding the SADT may result in a self-accelerating decomposition reaction with release of flammable vapors which may autoignite.

Do not taste or swallow.

Do not get in eyes, on skin, or on clothing.

Keep away from heat, sparks and flames.

No smoking.

Use only with adequate ventilation.

Wash thoroughly after handling.

Prevent product contamination.

Keep container tightly closed and away from combustible materials.

Keep only in the original container.

Check that all equipment is properly grounded and installed to satisfy electrical classification requirements.

Container hazardous when empty.

RESIDUAL VAPORS MAY EXPLODE ON IGNITION.

DO NOT CUT, DRILL, GRIND, OR WELD ON OR NEAR THIS CONTAINER.

Do not reuse container as it may retain hazardous product residue.

Improper disposal or reuse of this container may be dangerous and/or illegal.

Emptied container retains vapor and product residue.

Storage**General information on storage conditions:**

Keep away from direct sunlight. Keep container closed when not in use. Store in closed containers, in a secure area to prevent container damage and subsequent spillage. Outside or detached storage is preferred. Store in well ventilated area away from heat and sources of ignition such as flame, sparks and static electricity. Ensure that all storage and handling equipment is properly grounded and installed to satisfy electrical classification requirements. Store out of direct sunlight in a cool well-ventilated place. Store in original container. Store away from combustibles and materials to avoid. Refer also to National Fire Protection Association (NFPA) Code 400, Hazardous Materials Code. Static electricity may accumulate when transferring material. All metal and groundable storage containers, including but not limited to drums, cylinders, Returnable Intermodal Bulk Containers (RIBCs) and Class C Flexible Intermodal Bulk Containers (FIBCs) must be bonded and grounded during filling and emptying operations. Observe all federal, state and local regulations and National Fire Protection Association (NFPA) Codes which pertain to the specific local conditions of storage and use, including OSHA 29 CFR 1910.106 and NFPA 30, 70, 77, and 497.

Storage stability – Remarks:

Follow the recommended storage temperatures provided in this Section in order to maintain stability and oxygen content.

Storage incompatibility – General:

Store separate from:

Strong acids

Strong bases

Strong oxidizing agents

Reducing agents

Accelerators

Friedel - Crafts reaction catalyst

transition metal salts

metal ions

Sulphur compounds

Ketones

Brass

Copper

Iron

For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

Temperature tolerance – Do not store below:–

27 °F (-3 °C)

Temperature tolerance – Do not store above:

100 °F (38 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

Engineering controls:

Investigate engineering techniques to reduce exposures below airborne exposure limits or to otherwise reduce exposures. Provide ventilation if necessary to minimize exposures or to control exposure levels to below airborne exposure limits (if applicable see above). If practical, use local mechanical exhaust ventilation at sources of air contamination such as open process equipment.

Consult ACGIH ventilation manual or NFPA Standard 91 for design of exhaust systems.

Respiratory protection:

Where airborne exposure is likely or airborne exposure limits are exceeded (if applicable, see above), use NIOSH approved respiratory protection equipment appropriate to the material and/or its components. Full facepiece equipment is recommended and, if used, replaces need for face shield and/or chemical goggles. Consult respirator manufacturer to determine appropriate type equipment for a given application. Observe respirator use limitations specified by NIOSH or the manufacturer. For emergency and other conditions where there may be a potential for significant exposure or where exposure limit may be significantly exceeded, use an approved full face positive-pressure, self-contained breathing apparatus or positive-pressure airline with auxiliary self-contained air supply. Respiratory protection programs must comply with 29 CFR § 1910.134.

Skin protection:

Wear appropriate chemical resistant protective clothing and chemical resistant gloves to prevent skin contact. Consult glove manufacturer to determine appropriate type glove material for given application. Wear chemical goggles, a face shield, and chemical resistant clothing such as a rubber apron when splashing may occur. Rinse immediately if skin is contaminated. Remove contaminated clothing immediately and wash before reuse. Clean protective equipment before reuse. Provide a safety shower at any location where skin contact can

occur. Wash thoroughly after handling.

Eye protection:

Where there is potential for eye contact, wear a face shield, chemical goggles, and have eye flushing equipment immediately available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color:	colourless to slightly yellow
Physical state:	liquid
Odor:	Bleach-like
Odor threshold:	No data available
Flash point	approximately 109 °F (43 °C) (Method: closed cup)
Auto-ignition temperature:	approximately 460 °F (238 °C)
Lower flammable limit (LFL):	approximately 5.7 %(V)
Upper flammable limit (UFL):	approximately 99.99 %(V)
pH:	approximately 4.3
Density:	0.93 g/cm3 (77 °F (25 °C))
Specific Gravity (Relative density):	0.94 (77 °F (25 °C))Water=1 (liquid)
Vapor pressure:	approximately 23.00 mmHg (70 °F (21 °C))
Vapor density:	approximately 3.0 kg/m3 (77 °F (25 °C)) (Air = 1.0)
Boiling point/boiling range:	Decomposes before boiling. Rate of decomposition increases with rising temperature.
Melting point/range:	No data available.
Freezing point:	No data available.
Evaporation rate:	No data available
Solubility in water:	> 10 % 77 °F (25 °C)
Viscosity, kinematic:	approximately 0.04 mm2/s 68 °F (20 °C) (Method: Brookfield)
Viscosity, dynamic:	No data available
Oil/water partition	No data available

LUPEROX® TBH70X**coefficient:**

Self-Accelerating Decomposition Temperature (SADT): 190 °F (88 °C) 5 gallon container

Thermal decomposition No data available

Active oxygen content: 12.25 - 12.61 %

Flammability: See GHS Classification in Section 2

10. STABILITY AND REACTIVITY**Stability:**

This material is chemically unstable and should only be handled under specified conditions.

Hazardous reactions:

Hazardous polymerization does not occur.

Materials to avoid:

Strong acids
Strong bases
Strong oxidizing agents
Reducing agents
Accelerators
Friedel - Crafts reaction catalyst
transition metal salts
metal ions
Sulphur compounds
Ketones
Brass
Copper
Iron

For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

Conditions / hazards to avoid:

See HANDLING AND STORAGE section of this SDS for specified conditions. See Hazardous Decomposition Products below. SADT - Self Accelerating Decomposition Temperature. Lowest temperature at which the tested package size will undergo a self-accelerating decomposition reaction. This reaction will generate flammable vapors which may autoignite. The length of time to generate a decomposition reaction, after the SADT has been reached or exceeded, is dependent upon how much the SADT has been exceeded and the length of time needed for the reaction exotherm (heat spike from increasing decomposition rate) to initiate a rapid decomposition reaction. Typically, SADT is inversely proportional to package size. Larger packages will have a lower SADT due to smaller ratio to heat transfer area to volume of product.

Hazardous decomposition products:

Temperatures at or above SADT can result in the release of hazardous decomposition products which are flammable and may autoignite.

Thermal decomposition giving flammable and toxic products:

Carbon oxides
Hazardous organic compounds

11. TOXICOLOGICAL INFORMATION

Data on this material and/or a similar material are summarized below.

Data for LUPEROX® TBH70X**Acute toxicity****Oral:**

Acute toxicity estimate 580 mg/kg.

Dermal:

Acute toxicity estimate 428.57 mg/kg.

Inhalation:

4 h Acute toxicity estimate 2.64 mg/l.

Data for Hydroperoxide, 1,1-dimethylethyl (75-91-2)**Acute toxicity****Skin Irritation:**

Causes severe skin burns. (Rabbit) (24 h) (70 %) (occluded exposure, aqueous solution)

Causes mild skin irritation. (Guinea pig) (6 h) (5 %) (aqueous solution)

Eye Irritation:

Causes serious eye damage. (Rabbit) (70 %) (aqueous solution)

Skin Sensitization:

May cause an allergic skin reaction. Guinea pig maximization test. (Guinea pig) Skin allergy was observed. (Strong sensitizer)

Repeated dose toxicity

Repeated inhalation administration to Rat / affected organ(s): nose / signs: changes in body weight, irritation / (vapor)

Repeated oral administration to Rat / affected organ(s): stomach / signs: severe irritation

Genotoxicity**Assessment in Vitro:**

Genetic changes were observed in laboratory tests using: bacteria, animal cells

Genotoxicity**Assessment in Vivo:**

Both positive and negative responses for genetic changes were observed in laboratory tests using: mice

No genetic changes were observed in laboratory tests using: rats

Developmental toxicity

Exposure during pregnancy. oral (Rat) / No birth defects were observed. (at doses that produce effects in mothers)

Reproductive effects

Reproductive/Developmental Effects Screening Assay. oral (Rat) / No toxicity to reproduction.

12. ECOLOGICAL INFORMATION**Chemical Fate and Pathway**

Data on this material and/or a similar material are summarized below.

Data for Hydroperoxide, 1,1-dimethylethyl (75-91-2)**Biodegradation:**

Not readily biodegradable. (28 d) biodegradation 0 %

Octanol Water Partition Coefficient:

log Pow = 0.846 (Not expected to bioaccumulate.)

Photodegradation:

Air reaction with OH radicals Half-life direct photolysis: = 5.3 d

Ecotoxicology

Data on this material and/or a similar material are summarized below.

Data for Hydroperoxide, 1,1-dimethylethyl (75-91-2)**Aquatic toxicity data:**

Harmful. Pimephales promelas (fathead minnow) 48 h LC50 = 29.61 mg/l

Harmful. Poecilia reticulata (guppy) 96 h LC50 = 56.9 mg/l

Aquatic invertebrates:

Harmful. Daphnia magna (Water flea) 48 h EC50 = 14.1 mg/l

Algae:

Toxic. Algae 72 h EC50 = 1.5 mg/l

Microorganisms:

Slightly toxic. Respiration inhibition / Activated sludge 0.5 h EC50 = 17 mg/l

13. DISPOSAL CONSIDERATIONS**Waste disposal:**

Dilution followed by incineration is the preferred method. Dilution ratio of 10:1 in a clean, compatible, combustible solvent (i.e., Fuel Oil #2, mineral oil) will reduce reactivity hazard during incineration and transportation. Dispose of in accordance with federal, state and local regulations. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits. Note: Chemical additions to, processing of, or otherwise altering this material may make this waste management information incomplete, inaccurate, or otherwise inappropriate. Furthermore, state and local waste disposal requirements may be more restrictive or otherwise

different from federal laws and regulations.

Take appropriate measures to prevent release to the environment.

14. TRANSPORT INFORMATION

US Department of Transportation (DOT)

UN Number : 3109
 Proper shipping name : Organic peroxide type F, liquid
 Technical name : (Tert-Butyl hydroperoxide, <= 72%)
 Class : 5.2
 Subsidiary hazard class : (8)
 Packaging group : II
 Marine pollutant : yes

International Maritime Dangerous Goods Code (IMDG)

UN Number : 3109
 Proper shipping name : ORGANIC PEROXIDE TYPE F, LIQUID
 Technical name : (Tert-BUTYL HYDROPEROXIDE, <= 72%)
 Class : 5.2
 Marine pollutant : yes
 Flash point : approximately 109 °F (43 °C)

15. REGULATORY INFORMATION

Chemical Inventory Status

EU. EINECS	EINECS	Conforms to
United States TSCA Inventory	TSCA	The components of this product are all on the TSCA Inventory.
Canadian Domestic Substances List (DSL)	DSL	All components of this product are on the Canadian DSL
China. Inventory of Existing Chemical Substances in China (IECSC)	IECSC (CN)	Conforms to
Japan. ENCS - Existing and New Chemical Substances Inventory	ENCS (JP)	Conforms to
Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	Conforms to
Korea. Korean Existing Chemicals Inventory (KECI)	KECI (KR)	Conforms to
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	PICCS (PH)	Conforms to
Australia Inventory of Chemical Substances (AICS)	AICS	Conforms to

LUPEROX® TBH70X**United States – Federal Regulations****SARA Title III – Section 302 Extremely Hazardous Chemicals:**

The components in this product are either not SARA Section 302 regulated or regulated but present in negligible concentrations.

SARA Title III - Section 311/312 Hazard Categories:

Acute Health Hazard, Chronic Health Hazard, Fire Hazard, Reactivity Hazard

SARA Title III – Section 313 Toxic Chemicals:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):

<u>Chemical Name</u>	<u>CAS-No.</u>	<u>Reportable quantity</u>
Hydroperoxide, 1,1-dimethylethyl	75-91-2	100 lbs

United States – State Regulations**New Jersey Right to Know**

<u>Chemical Name</u>	<u>CAS-No.</u>
Hydroperoxide, 1,1-dimethylethyl	75-91-2

New Jersey Right to Know – Special Health Hazard Substance(s)

<u>Chemical Name</u>	<u>CAS-No.</u>
Hydroperoxide, 1,1-dimethylethyl	75-91-2

Pennsylvania Right to Know

<u>Chemical Name</u>	<u>CAS-No.</u>
Hydroperoxide, 1,1-dimethylethyl	75-91-2

Water	7732-18-5
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California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive defects.

16. OTHER INFORMATION

LUPEROX® TBH70X**Full text of H-Statements referred to under sections 2 and 3.**

H226	Flammable liquid and vapour.
H242	Heating may cause a fire.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H331	Toxic if inhaled.
H341	Suspected of causing genetic defects.
H411	Toxic to aquatic life with long lasting effects.

HMIS ratings:

Health:	3 (SERIOUS HAZARD)
Fire:	2 (MODERATE HAZARD)
Physical Hazard:	1 (SLIGHT HAZARD)

Miscellaneous:

Other information:	Refer to National Fire Protection Association (NFPA) Codes 30, 70, 77, and 497 and OSHA 29 CFR 1910.106, for safe handling.
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Latest Revision(s):

Reference number:	000000034016
Date of Revision:	10/18/2015
Date Printed:	11/29/2016

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The statements, technical information and recommendations contained herein are believed to be accurate as of the date hereof. Since the conditions and methods of use of the product and of the information referred to herein are beyond our control, ARKEMA expressly disclaims any and all liability as to any results obtained or arising from any use of the product or reliance on such information; **NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE GOODS DESCRIBED OR THE INFORMATION PROVIDED HEREIN.** The information provided herein relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process. The user should thoroughly test any application before commercialization. Nothing contained herein constitutes a license to practice under any patent and it should not be construed as an inducement to infringe any patent and the user is advised to take appropriate steps to be sure that any proposed use of the product will not result in patent infringement. See SDS for Health & Safety Considerations.

Arkema has implemented a Medical Policy regarding the use of Arkema products in Medical Devices applications that are in contact with the body or circulating bodily fluids (<http://www.arkema.com/en/social-responsibility/responsible-product-management/medical-device-policy/index.html>) Arkema has designated Medical grades to be used for such Medical Device applications. Products that have not been designated as Medical grades are not authorized by Arkema for use in Medical Device applications that are in contact with the body or circulating bodily fluids. In addition, Arkema strictly prohibits the use of any Arkema products in Medical Device applications that are implanted in the body or in contact with bodily fluids or tissues for greater than 30 days. The Arkema trademarks and the Arkema name shall not be used in conjunction with customers' medical devices, including without limitation, permanent or temporary implantable devices, and customers shall not represent to anyone else, that Arkema allows, endorses or permits the use of Arkema products in such medical devices.

It is the sole responsibility of the manufacturer of the medical device to determine the suitability (including biocompatibility) of all raw materials, products and components, including any medical grade Arkema products, in order to ensure that the final end-use product is safe for its end use; performs or functions as intended; and complies with all applicable legal and regulatory requirements (FDA or other national drug agencies) It is the sole responsibility of the manufacturer of the medical device to conduct all necessary

tests and inspections and to evaluate the medical device under actual end-use requirements and to adequately advise and warn purchasers, users, and/or learned intermediaries (such as physicians) of pertinent risks and fulfill any postmarket surveillance obligations. Any decision regarding the appropriateness of a particular Arkema material in a particular medical device should be based on the judgment of the manufacturer, seller, the competent authority, and the treating physician.